Congress of the United States
Washington, DC 20515

October 6, 2003

Mark B. McClellan
Commissioner
United States Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner McClellan,

We are writing to address the FDA's recent claim that a series of "blitz exams" of prescription drug shipments indicates that open prescription drug markets are unsafe. We believe firmly that these inspections underscore the importance of H.R. 2427, the Pharmaceutical Market Access Act, and similar legislation, which would actually improve the safety of our nation's drug supply.

The FDA's timing is impeccable. At exactly the time the pharmaceutical industry is spending millions to defeat the prescription drug market access legislation overwhelmingly passed by the House of Representatives in July, your agency has suddenly become active in highlighting the perils of pharmaceutical products entering the U.S. market from abroad.

By the FDA's own admission, the "investigation" that led to these findings was not scientific. None of the seized drug samples were actually tested. While FDA Senior Associate Commissioner Hubbard admitted that most of the inspected drugs would not be legal if the language in H.R. 2427 were enacted, the findings imply that H.R. 2427 and similar legislation would make all of the seized packages legal.

It is disheartening that instead of working with the Congress to find common solutions for lowering drug prices and ensuring the safety of the drug supply, the FDA is spending its resources to produce inflammatory, unscientific attacks on legislation that stands to benefit all Americans.

As you know, the market access legislation we advocate would limit access to prescription drugs to twenty-five specific countries. This list of countries was written into current statute by the advice of FDA lawyers in the year 2000. The list of countries in current statute (21 U.S.C. 384) does not include any of the less vigorously regulated markets, such as India, Thailand and the Philippines, that the FDA cited in its examinations. Furthermore, it would not permit the import of controlled substances or unapproved medicines. Quite to the contrary, H.R. 2427 would permit and strictly limit the importation of prescription drugs to only FDA-approved medicines manufactured in FDA-inspected and approved facilities. It would also require anti-counterfeiting

packaging, superior to that which is presently used in the U.S. market. This technology would ensure that the billions of dollars of medications already imported annually by pharmaceutical companies, as well as drugs that could be imported by wholesalers, pharmacists, and individuals, are safe.

Though opponents of this legislation would like to present the results of this FDA "study" as an indication that drug importation can never be safe, it actually reveals how profoundly we need to pass meaningful legislation that provides Americans access to the lower drug prices available in other industrialized countries.

The fact that many Americans simply cannot afford the drugs they need propels the market for non-FDA-approved drugs in the United States. Far too many Americans resort to unapproved methods of purchasing drugs because they believe they have no other option.

An article in last Monday's Wall Street Journal discussed loopholes in the drug distribution system involving the role of drug wholesalers and indicated that, despite claims from the pharmaceutical industry, the drug distribution system as it exists today is not airtight. Not only would drug importation legislation increase the affordability of drugs in this country, but it would put into effect needed safety precautions which are available today and should already be in use.

In our country today, nearly thirty percent of seniors cannot afford to purchase the medicine their doctors prescribe. Given the FDA's concern about safety, we wonder why your agency has not yet investigated how many Americans die or become more ill because they cannot afford the high cost of prescription drugs. Instead, the FDA has dramatically stepped up its enforcement activities in recent months against the million or more Americans now buying prescription drugs safely from Canada each year. Perhaps the FDA's budget would be better allocated toward a study of how many Americans will see a deterioration of their health if they are cut off from the life-saving medicines they are now able to afford only by purchasing on the Canadian and other well-regulated markets.

We believe that this matter is of such importance to the American people that we would like to meet with you at your earliest convenience to discuss the FDA's recent announcement and its position on the pending proposals to enable Americans to access safe and affordable prescription drugs from other well-regulated countries. Our staff will follow up with yours to work out a mutually agreeable time.

Sincerely,

Bernard Sanders	Gil Gutknecht	Rahm Emanuel
Member of Congress	Member of Congress	Member of Congress

Dan Burton
Member of Congress

Rosa DeLauro
Member of Congress

Jo Ann Emerson
Member of Congress

Marion Berry
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